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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,945	06/08/2001	Ulf Smith	45069	8408

466 7590 09/24/2002

YOUNG & THOMPSON
745 SOUTH 23RD STREET 2ND FLOOR
ARLINGTON, VA 22202

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/24/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/875,945	SMITH, ULF	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 June 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121:
 - I. Claims 1-6, drawn to an isolated, substantially purified nucleotide sequence, requiring SEQ ID Nos. 1-12, classified in class 536, and subclass 23.1.
 - II. Claims 7-16, and 32, drawn to a method of evaluating or screening substances for insulin regulating properties, requiring SEQ ID Nos. 1-12, classified in class 436, and subclass 501.
 - III. Claims 17, 30-31, 33, drawn to a substance identified as having insulin regulating properties, a pharmaceutical composition, a veterinary preparation, requiring SEQ ID Nos. 1-12 classified in class 514, and subclass 2.
 - IV. Claims 18-25, drawn to use of a nucleotide sequence as medicament, veterinary preparation, requiring SEQ ID Nos. 1-12, classified in class 514, and subclass 44.
 - V. Claims 26-29, drawn to use of a substance as medicament, veterinary preparation, requiring SEQ ID Nos. 1-12, classified in class 424, and subclass 9.411.
 - VI. Claims 34-35, drawn to a method of diagnosis of IRS-2 related metabolic disorders, requiring SEQ ID Nos. 1-12, classified in class 435, subclass 6.
 - VII. Claims 36-39, drawn a method for determining if a patient in need of treatment, requiring SEQ ID Nos. 1-12, classified in class 424, subclass 9.2.
2. The inventions are distinct, each from the other because of the following:

Inventions I and IV, VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the product as claimed in Group I can be used in purification assays or polymerase chain reaction assays.

Inventions III and II, V, VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the product as claimed in Group III can be used in immunological assays and ligand binding assays.

Inventions in Group II, V, VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method steps of Group II, V, VII can be used independently from each other because the end result of the method steps in Groups II, V and VII yield different results and have different functions. For example, the method of Group II results in selection of substance that has insulin regulating properties, whereas, the method of Group V results in selecting substance as medicament, and whereas the method of Group VII determines whether a patient is in need of treatment.

Inventions in Group IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method steps of Group IV and V can be used independently from each other because the end

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result of the method steps in Groups IV and V yield different results and have different modes of operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and the search for one group is not required for any other group, restriction for examination purposes as indicated is proper.

In this application additionally, no matter which restriction group applicant elects, applicant is required to specify a restricted subgroup (one specific nucleotide sequence) for examination. This requirement is made under 1192 O.G. 68 Notice (November 19, 1996 and revised M.P.E.P.), as the examination of more than one sequence in the application would result in an undue search burden on the PTO.

In order to be perfectly clear, the following subgroups within the Groups are NOT species election. Each nucleic acid sequence is independent and distinct because specific nucleic acid is structurally and functionally distinct from each other specific nucleic acid molecules. The chemical structure of each nucleic acid molecule and each molecule containing the same differ from each other. For example, a polynucleotide comprising SEQ ID NO: 1 is chemically, structurally, and functionally different from a molecule comprising an allele SEQ ID NO. 2.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

SC
Suryaprabha Chunduru
September 19, 2002

[Signature]
JEFFREY FREDMAN
PRIMARY EXAMINER